

Amendments to the Claims:

Please amend the heading at page 70, line 1, to delete the underlining so that it appears as:

WHAT WE CLAIM IS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) ~~A pharmaceutical~~ **Pharmaceutical** combination comprising at least:

- A a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives thereof, and

- A a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaine of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof with the ~~provision~~ proviso that said second compound is different from the first compound,

in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least ~~3~~ 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

2. (currently amended) The combination of claim 1, which comprises an amount of said first compound, calculated as acetylsalicylic acid, of less than 85 mg, ~~advantageously of less than 75 mg, preferably of less than 60 mg.~~

3. (currently amended) The combination of claim 1, which comprises an amount of a compound selected from the group consisting of acetylsalicylic acid ~~or a~~ pharmaceutical derivative thereof and mixtures thereof corresponding to 3 to 80 mg, ~~advantageously from 5 to 75 mg, preferably from 10 to 75 mg~~ calculated as acetylsalicylic acid.

5 4. (currently amended) The combination of claim 1, in which the amount of second compound is at least comprised between 3 5 and 100 times the amount calculated as acetylsalicylic acid weight of said first compound, ~~advantageously comprised between 5 and 25 times the amount calculated as acetylsalicylic acid weight of said first compound.~~

10 5. (previously presented) The combination of claim 1 as an unitary dose, in which the amount of second compound is 60 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

15 6. (previously presented) The combination of claim 1, which is prepared at least from a mixture in which at least 50% by weight of the first compound and at least 50% of the second compound are in soluble form.

20 7. (previously presented) The combination of claim 1, which is prepared at least from a mixture in which at least 90% by weight of the first compound and at least 90% of the second compound are in soluble form.

25 8. (previously presented) The combination of claim 1, which is prepared at least from a mixture in which the first compound and the second compound are substantially completely in soluble form.

9. (previously presented) The combination of claim 1, which the second compound is at least in a controlled release form.

30 10. (previously presented) The combination of claim 1, which the first compound is at least partly in an immediate release form.

Application No. (Attorney Docket No. 36163)
Inventors: Jallal MESSADEK et al.
Title: BETAINE COMPOSITIONS
Preliminary Amendment

5 11. (currently amended) The combination of claim 1, which comprises dry particles;
~~especially micro-particules~~, prepared by drying a mixture in which the first compound and the
second compound are partly in a soluble form.

10 12. (previously presented) The combination of claim 1, in which the first compound and the
second compound are combined in the form selected from the group consisting of a matrix, a
gel, an hydrogel, a wax and a porous carrier, a bilayered tablet and combination thereof.

15 13. (previously presented) The combination of claim 1, which further comprises at least one
compound reacting in presence of water so as to prepare substantially immediately a solution
or suspension of first compound and second compound.

14. (currently amended) The combination of claim 1 in which the second compound
comprises at least glycine betaine monohydrate.

20 15. (currently amended) The combination of claim 1 in which the second compound
comprises at least glycine betaine anhydrous.

16. (currently amended) Pharmaceutical unit dosage form comprising at least a pharmaceutical combination containing at least:

A - a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives thereof, and

A - a second compound selected from the group consisting of lipidic betaines, betaines lipid, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, or a pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound, in which the combination is prepared from a mixture in which the first compound and the second compound are partly in a soluble form.

17. (currently amended) The pharmaceutical form according to claim 16, which comprises ~~less than 500 mg, advantageously less than 300 mg, preferably~~ less than 100 mg of said first compound expressed as acetylsalicylic acid.

18. (currently amended) The pharmaceutical form according to claim 16, in which the amount of second compound is at least 3 5 times the amount by weight of said first compound expressed as acetylsalicylic acid.

19. (previously presented) The pharmaceutical form of claim 16, in which the combination is prepared from a mixture in which at least 50% by weight of the first compound and at least 50% of the second compound are in soluble form.

20. (previously presented) The pharmaceutical form of claim 16, in which the combination is prepared from a mixture in which at least 90% by weight of the first compound and at least 90% of the second compound are in soluble form.

21. (previously presented) The pharmaceutical form of claim 16, in which the combination is prepared from a mixture in which the first compound and the second compound are substantially completely in soluble form.

22. (currently amended) The pharmaceutical form of claim 16, in which the combination is in the form of dry particles ~~, especially micro-particles,~~ prepared by drying a mixture in which the first compound and the second compound are partly in a soluble form.

23. (previously presented) The pharmaceutical form of claim 16, in which the combination is in the form selected from the group consisting of a matrix, a gel, an hydrogel, a wax and a porous carrier and combinations thereof.

24. (previously presented) The pharmaceutical form of claim 16, which is at least a controlled release formulation for the second compound.

25. (previously presented) The pharmaceutical form of claim 16, which is at least an immediate release formulation for the first compound.

26. (previously presented) The pharmaceutical form of claim 16, which further comprises at least one compound reacting in presence of water so as to prepare substantially immediately a solution or suspension of first compound and second compound.

27. (currently amended) The pharmaceutical form of claim 16, in which second compound is selected from the group consisting of glycine betaine or a pharmaceutical salt thereof.

28. (currently amended) A kit for a daily administration, said kit comprising at least:

- ~~An~~ a first oral formulation comprising a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives thereof, and
- A a second oral formulation comprising a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, or a pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound

in which the first oral formulation comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound in the second oral formulation is at least ~~three~~ five times the amount, calculated as acetylsalicylic acid, of said first compound.

29. (currently amended) The kit of claim 28, in which the first oral formulation comprises an amount of said first compound, calculated as acetylsalicylic acid, of less than 85 mg ; ~~advantageously of less than 75 mg, preferably of less than 60 mg.~~

30. (currently amended) The kit of claim 28, in which the first oral formulation comprises an amount of a compound selected among the group consisting of acetylsalicylic acid ~~or~~, pharmaceutical derivative thereof and mixtures thereof corresponding to 3 to 80 mg ; ~~advantageously from 5 to 75 mg, preferably from 10 to 75 mg~~ calculated as acetylsalicylic acid.

~~31. (cancelled) The kit of claim 28, in which the second oral formulation comprises an amount of second compound corresponding to at least 5 times the amount by weight, ealeulated as acetylsalicylic acid, of said first compound.~~

Application No. (Attorney Docket No. 36163)

Inventors: Jallal MESSADEK et al.

Title: BETAINES COMPOSITIONS

Preliminary Amendment

5 32. (currently amended) The kit of claim 28, ~~in~~ in which the second oral formulation comprises an amount of second compound corresponding to 10 times to 100 times by weight, calculated as acetylsalicylic acid, of said first compound.

10 33. (currently amended) The kit of claim 28, in which the first oral formulation comprises an amount of a second compound selected from the group consisting of betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound.

15 34. (previously presented) The kit of claim 28, in which the first oral formulation is prepared at least from a mixture in which at least 50% by weight of the first compound and at least 50% of the second compound are in soluble form.

20 35. (previously presented) The kit of claim 28, in which the first oral formulation is prepared at least from a mixture in which at least 90% by weight of the first compound and at least 90% of the second compound are in soluble form.

25 36. (previously presented) The kit of claim 28, in which the first oral formulation is prepared at least from a mixture in which the first compound and the second compound are substantially completely in soluble form.

37. (currently amended) The kit of claim 28, ~~in~~ in which the second oral compound is at least in a controlled release form.

30 38. (previously presented) The kit of claim 28, in which the first oral compound is at least in an immediate release form.

39. (currently amended) The kit of claim 28, in which the second oral formulation is ~~at least~~
selected among the group consisting of glycine betaine and its pharmaceutically acceptable
salts.

40. (currently amended) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and
- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical combination ~~according to anyone of the claims 1 to 15 or a pharmaceutical dosage form according to anyone of the claims 16 to 27 or a kit according to any one of the claims 28 to 39~~, for treating or preventing blood flow disturbances, said combination comprising at least the first compound and the second compound,

in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

41. (currently amended) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical combination ~~according to anyone of the claims 1 to 15 or a pharmaceutical dosage form according to anyone of the claims 16 to 27 or a kit according to any one of the claims 28 to 39~~, for treating or preventing cancer, said combination comprising at least the first compound and the second compound,
in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

42. (currently amended) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical combination ~~according to anyone of the claims 1 to 15 or a pharmaceutical dosage form according to anyone of the claims 16 to 27 or a kit according to any one of the claims 28 to 39~~, for treating or preventing diabetes, said combination comprising at least the first compound and the second compound,

in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

43. (currently amended) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical combination ~~according to anyone of the claims 1 to 15 or a pharmaceutical dosage form according to anyone of the claims 16 to 27 or a kit according to any one of the claims 28 to 39~~, for treating or preventing gut, said combination comprising at least the first compound and the second compound,

in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

44. (currently amended) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the ~~provision~~ proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical combination ~~according to anyone of the claims 1 to 15 or a pharmaceutical dosage form according to anyone of the claims 16 to 27 or a kit according to any one of the claims 28 to 39~~, for treating or preventing inflammation, said combination comprising at least the first compound and the second compound,
in which said combination comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

45. (currently amended) Process of treatment of a patient in need for treating, preventing, reducing thrombosis troubles for a patient, by administering to said patient ~~a pharmaceutical combination according to anyone of the claims 1 to 15 or a pharmaceutical unit dose according to anyone of the claims 16 to 27~~ less than 100 ml of a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives thereof, and

~~in which advantageously before and/or during and/or after said administration,~~ a therapeutic effective amount of glycine betaine is further administered to said patient, said amount of glycine betaine is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

5 46. (currently amended) Process of treatment of a patient in need for treating, preventing,
reducing inflammation troubles in a patient, by administering to said patient ~~a pharmaceutical~~
~~combination according to anyone of the claims 1 to 15 or a pharmaceutical unit dose~~
~~according to anyone of the claims 16 to 27~~ less than 100 ml of a first compound selected
10 among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives
thereof, and

in which ~~advantageously before and/or during and/or after said administration,~~ a therapeutic
effective amount of glycine betaine is further administered to said patient, said amount of
glycine betaine is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said
15 first compound.

47. (currently amended) Process of treatment of a patient in need for treating, preventing,
reducing inflammation troubles in a patient, by administering to said patient ~~a pharmaceutical~~
~~combination according to anyone of the claims 1 to 15 or a pharmaceutical unit dose~~
~~according to anyone of the claims 16 to 27~~ less than 100 ml of a first compound selected
20 among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives
thereof, and

in which ~~advantageously before and/or during and/or after said administration,~~ a therapeutic
effective amount of glycine betaine is further administered to said patient, said amount of
glycine betaine is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said
25 first compound.

5 48. (currently amended) Process of treatment of a patient in need for treating, preventing,
reducing inflammation troubles in a patient, by administering to said patient ~~a pharmaceutical~~
~~combination according to anyone of the claims 1 to 15 or a pharmaceutical unit dose~~
~~according to anyone of the claims 16 to 27~~ less than 100 ml of a first compound selected
10 among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives
thereof, and

in which ~~advantageously before and/or during and/or after said administration,~~ a therapeutic
effective amount of glycine betaine is further administered to said patient, said amount of
glycine betaine is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said
15 first compound.

49. (currently amended) Process of treatment of a patient in need for treating, preventing,
reducing gut troubles in a patient, by administering to said patient ~~a pharmaceutical~~
~~combination according to anyone of the claims 1 to 15 or a pharmaceutical unit dose~~
~~according to anyone of the claims 16 to 27~~ less than 100 ml of a first compound selected
20 among the group consisting acetylsalicylic acid, salicylic acid, and pharmaceutical derivatives
thereof, and

in which ~~advantageously before and/or during and/or after said administration,~~ a therapeutic
effective amount of glycine betaine is further administered to said patient, said amount of
glycine betaine is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said
25 first compound.

50. (currently amended) A pharmaceutical composition comprising a betaine and aspirin in a
formulation wherein the betaine and aspirin are formulated together in a bilayered tablet, the
30 aspirin being present in a first layer, and the betaine being present in a second layer in an
amount at least ~~three~~ five times the amount of aspirin.

5 51. (previously presented) The pharmaceutical composition as defined in claim 50, wherein the layer containing the betaine also includes one or more buffering agents.

10 52. (previously presented) The pharmaceutical composition as defined in claim 50, wherein the tablet includes a core and a coating layer surrounding said core and wherein one of the betaine and aspirin is present in the core and the other is present in a coating layer surrounding the core.

15 53. (previously presented) The pharmaceutical composition as defined in claim 50, wherein the tablet includes a core and a coating layer surrounding said core and wherein a mixture of the betaine and aspirin is present in the core and one of the betaine and aspirin is present in the coating layer surrounding the core.

20 54. (previously presented) The pharmaceutical composition as defined in claim 52, wherein the aspirin is present in the core and the betaine is present in the coating layer.

55. (currently amended) The pharmaceutical composition as defined in ~~anyone of the claims~~ claim 52 to 54, wherein the aspirin is present in the core and the betaine present in the coating layer is in a controlled release form.

25 56. (currently amended) The pharmaceutical composition as defined in ~~anyone of the claims~~ claim 52 to 54, wherein the betaine is present in the core in a controlled release form and the aspirin is present in the coating layer.

30 57. (currently amended) The pharmaceutical composition as defined in claim 53 wherein the coating layer also includes at least one buffering agent ~~or more buffering agents~~.

5 58. (currently amended) The pharmaceutical composition as defined in claim 54 wherein the coating layer also includes at least one ~~or more~~ buffering agent ~~agents~~ and at least one ~~or more~~ protecting film ~~films~~.

10 59. (previously presented) The pharmaceutical composition as defined in claim 50 wherein the betaine is selected from the group consisting of betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof.

15 60. (previously presented) The pharmaceutical composition as defined in claim 50 further including an outer protective coating or finishing layer surrounding said tablet.

61. (previously presented) The pharmaceutical composition as defined in claim 50 wherein the aspirin is in the form of enteric coated aspirin granules.

20 62. (currently amended) The pharmaceutical composition as defined in claim ~~4~~ 50 in the form of a bilayered tablet which comprises a first layer comprising aspirin granules and at least one ~~or more~~ excipient ~~excipients~~, and a second layer comprising a betaine and at least one ~~or more~~ buffering compound ~~compounds~~ and at least one ~~or more~~ excipient ~~excipients~~.

25 63. (currently amended) The pharmaceutical composition as defined in claim 60, wherein the first layer comprises aspirin granules; and at least one ~~or more~~ bulking agent ~~agents~~ ~~and optionally a lubricant~~, and the second layer comprises a betaine, ~~optionally a wet granulating agent, one or more buffering compounds selected from the group consisting of calcium carbonate, magnesium oxide, magnesium carbonate and mixtures thereof, and optionally~~
30 ~~magnesium stearate~~.

Application No. (Attorney Docket No. 36163)
Inventors: Jallal MESSADEK et al.
Title: BETAINES COMPOSITIONS
Preliminary Amendment

5 64. (currently amended) The pharmaceutical composition ~~compositions as defined in anyone~~
of the ~~claims~~ claim 50 ~~to 63~~ further including an outer protective coating surrounding said
bilayered tablet.

10 65. (currently amended) The pharmaceutical composition ~~compositions as defined in anyone~~
of the ~~claims~~ claim 50 ~~to 63~~ further including an antithrombotic agent.

66. (currently amended) The pharmaceutical composition ~~compositions as defined in anyone~~
of the ~~claims~~ claim 50 ~~to 63~~ further including an anti cancerous agent.

15 67. (currently amended) The pharmaceutical ~~composition as defined in anyone~~ of the ~~claims~~
claim 50 ~~to 63~~ further including an anti inflammatory agent.

20 68. (currently amended) The pharmaceutical ~~composition as defined in anyone~~ of the ~~claims~~
claim 50 ~~to 63~~ further including an antibiotic agent.

69. (currently amended) The pharmaceutical ~~composition as defined in anyone~~ of the ~~claims~~
claim 50 ~~to 63~~ further including an anti diabetic agent.

25 70. (currently amended) The pharmaceutical ~~composition as defined in anyone~~ of the ~~claims~~
claim 50 ~~to 63~~ further including an antioxidant agent.

5 71. (currently amended) A method for ~~preventing or inhibiting or~~ treating a patient suffering
from atherosclerosis ~~or reducing risk of or treating a cardiovascular event or disease,~~
~~coronary artery disease or cerebrovascular disease,~~ which comprises administering to the a
patient in need of treatment a therapeutically effective amount of a pharmaceutical
composition ~~according to claim 50~~ comprising a betaine and aspirin in a formulation wherein
10 the betaine and aspirin are formulated together in a bilayered tablet, the aspirin being present
in a first layer, and the betaine being present in a second layer in an amount at least five times
the amount of aspirin.

15 72. (previously presented) The method ~~of as defined in~~ claim 71, wherein the betaine
employed is selected from the group consisting of anhydrous betaine, and/or betaine
monohydrate salt, ~~and/or~~ lipidic betaine and ~~or~~ betaine lipids.

20 73. (previously presented) A pharmaceutical composition comprising betaine and aspirin in
a formulation to reduce aspirin side effects wherein the betaine and aspirin are formulated
together in a bilayered tablet, the aspirin being present in a first layer, and the betaine being
present in a second layer.

25 74. (previously presented) A pharmaceutical composition comprising betaine and aspirin in
a formulation to increase aspirin therapeutic effects wherein the betaine and aspirin are
formulated together in a bilayered tablet, the aspirin being present in a first layer, and the
betaine being present in a second layer.

30 75. (new) The combination of claim 1, which comprises an amount of said first
compound, calculated as acetylsalicylic acid, of less than 75 mg.

76. (new) The combination of claim 1, which comprises an amount of said first
compound, calculated as acetylsalicylic acid, of less than 60 mg.

- 5 77. (new) The combination of claim 1, which comprises an amount of a compound selected from the group consisting of acetylsalicylic acid, pharmaceutical derivative thereof and mixtures thereof corresponding to advantageously from 5 to 75 mg calculated as acetylsalicylic acid.
- 10 78. (new) The combination of claim 1, which comprises an amount of a compound selected from the group consisting of acetylsalicylic acid, pharmaceutical derivative thereof and mixtures thereof corresponding to advantageously from 10 to 75 mg calculated as acetylsalicylic acid.
- 15 79. (new) The combination of claim 1, in which the amount of second compound is at least comprised between 5 and 25 times the amount calculated as acetylsalicylic acid weight of said first compound.
- 20 80. (new) The combination of claim 1, which comprises dry micro particles prepared by drying a mixture in which the first compound and the second compound are partly in a soluble form.
- 25 81. (new) The pharmaceutical form of claim 16, in which the combination is in the form of dry micro particles prepared by drying a mixture in which the first compound and the second compound are partly in a soluble form.
- 30 82. (new) The kit of claim 28, in which the first oral formulation comprises an amount of said first compound, calculated as acetylsalicylic acid, of less than 75 mg.
83. (new) The kit of claim 28, in which the first oral formulation comprises an amount of said first compound, calculated as acetylsalicylic acid, of less than 60 mg.

5 84. (new) The kit of claim 28, in which the first oral formulation comprises an amount of a compound selected among the group consisting of acetylsalicylic acid, pharmaceutical derivative thereof and mixtures thereof from 5 to 75 mg, calculated as acetylsalicylic acid.

10 85. (new) The kit of claim 28, in which the first oral formulation comprises an amount of a compound selected among the group consisting of acetylsalicylic acid, pharmaceutical derivative thereof and mixtures thereof from 10 to 75 mg, calculated as acetylsalicylic acid.

86. (new) The use of

15 - a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the proviso that said second compound is different from the first compound,

20 for the preparation of a pharmaceutical unit dosage form for treating or preventing blood flow disturbances, said unit dosage form comprising at least a first compound, and a second compound,

25 in which said unit dosage form comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

87. (new) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical unit dosage form for treating or preventing cancer, said unit dosage form comprising at least a first compound and a second compound,

in which said unit dosage form comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

5 88. (new) The use of

- a first compound selected among the group consisting acetylsalicylic acid, salicylic acid, pharmaceutical derivatives thereof, and

- a second compound selected from the group consisting of lipidic betaines, betaines
10 lipids, betaines of formula $(\text{CH}_3)_3\text{N}^+(\text{CH}_2)_n\text{COO}^-$ with n an integer from 1 to 5, pharmaceutically acceptable salts thereof, esters thereof, precursors thereof, and mixtures thereof, with the proviso that said second compound is different from the first compound,

for the preparation of a pharmaceutical unit dosage form for treating or preventing diabetes, said unit dosage form comprising at least: a first compound and a second
15 compound,

in which said unit dosage form comprises less than 100 mg of said first compound expressed as acetylsalicylic acid, and

in which the amount of second compound is at least 5 times the amount, calculated as acetylsalicylic acid weight, of said first compound.

20 89. (new) The pharmaceutical composition of claim 60, wherein the first layer comprises aspirin granules and at least one bulking agent and optionally a lubricant, and the second layer comprises a betaine and at least one buffering compound selected from the group consisting of calcium carbonate, magnesium oxide, magnesium carbonate and mixtures thereof.
25

90. (new) A method for reducing risk of an event selected from the group consisting of cardiovascular events, coronary artery troubles and cerebro-vascular troubles, which comprises administering to the patient at risk of such an event a therapeutically effective
30 amount of a pharmaceutical composition comprising a betaine and aspirin in a formulation wherein the betaine and aspirin are formulated together in a bilayered tablet, the aspirin being present in a first layer, and the betaine being present in a second layer in an amount at least five times the amount of aspirin.

Application No. (Attorney Docket No. 36163)

Inventors: Jallal MESSADEK et al.

Title: BETAINES COMPOSITIONS

Preliminary Amendment

5 91. (new) The method of claim 90, wherein the betaine employed is selected from the group
consisting of anhydrous betaine, betaine monohydrate salt, lipidic betaine and betaine lipids.

10

15

20

25

30